



September 16, 1999

Food and Drug Administration
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, D.C. 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Arkopharma, Inc., 432 Fairfield Avenue Stamford, CT 06902, within the past 30 days commenced marketing a dietary supplement bearing the following statements on the label and/or in the labeling:

Text of Claims:

1. the antioxidant nutritional supplement with a heart
2. Studies have suggested a close relationship between the moderate consumption of red wine and a healthy heart. This phenomenon has been named the French Paradox because although the French eat as much saturated fat as Americans, they seem to enjoy better overall cardiovascular health.
3. French Parad'ox supplies polyphenols and anthocyanosides, the active ingredients believed to be responsible for the benefits of red wine. Added to a healthy lifestyle, French Parad'ox capsules will give you the benefit of red wine without the alcohol.

Name of Ingredients Subject to Claim: red wine marc extract

Name of Supplement: Arkopharma *French Parad'ox*

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma has substantiation that the statement is truthful and not misleading.

Sincerely,

David M. Kulow
President

Sales, Marketing & Finance Office
53 Shore Road
Winchester, MA 01890
Tel: (781) 721-3303
Fax: (781) 290-5851
A Division of Oakmont Investment Co. Inc.

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